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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,128	09/26/2000	E. Premkumar Reddy	6056-251-CT1	5662

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/670,128	REDDY ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 January 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) 1-12, 14 and 17-29 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 13, 15-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Response to Arguments

The Response filed January 28, 2003 (Paper No. 14) in response to the Office Action of October 22, 2002 is acknowledged and has been entered.

Claims 1-29 are pending.

Claims 1-12, 14, and 17-29 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 13, and 15-16 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 13, and 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia *et al.* (Cell Growth & Differentiation, Vol.8, pages 1267-1276, December 1997, IDS) and Takemoto *et al.* (Proc.Natl.Acad.Sci., Vol. 94, December 1997, pages 13897-13902) as further evidenced by (Univ. Mich Med. School, Proc. Ann. Meet. Assoc. Cancer Res., 1997, 38, A3725, meeting abstract) for the reasons of record in Paper No. 13, pages 2-7.

Applicants argue (Paper No. 14, page 2) that the Examiner has alleged that Garcia shows a correlation between STAT-3 activation and metastatic potential. This is not the case. The teachings of Garcia were clearly outlined in Paper No. 13, page 3, Item 1. Applicants further contend that the only correlation (emphasis added) recognized by Garcia is between STAT-3 activation and transformation of cancer cells by src. This argument has been considered but is not found persuasive because, as pointed out in Paper No. 13, page 3, Item 1, Garcia also teach that studies of primary tumors indicate that elevated STAT3 activation also occurs in human breast tumors compared to adjacent normal tissue (page 1274, 1st column, 1st paragraph) and that, overall, constitutive activation of Stat3 is a frequent event in breast carcinoma cells. Applicants further re-address the issue that “transformation is a necessary but not universally sufficient event for metastasis”. This argument has been considered but is not found persuasive for the reasons of record in Paper No. 13, page 5.

Applicants further argue that the Examiner cites Takemoto only for the proposition that STAT-3 can be sampled in cancer patients, and that one of ordinary skill in the art would not consider the evidence that STAT-3 activation is also correlated with metastatic potential. Applicants further argue that the examiner admits that the combination of Garcia and Takemoto does not reasonably suggest to one skilled in the art that activated STAT-3 can successfully be used as an indicator of tumor metastasis. This argument has been considered but is not found persuasive because there was no such admission on the record; only that a new rejection was made because new art pertaining to the previous rejection had become available. In other words, there is no admission on the record that alone, Garcia and Takemoto, do not suggest to one

skilled in the art that activated STAT-3 can successfully be used as an indicator of tumor metastasis.

Applicants further argue that in an attempt to cure the deficiencies of Garcia and Takemoto, the Examiner now alleges that the UMich abstract shows metastatic (as opposed to merely transformed) breast cancer cells have high levels of activated Stat-3. This argument has been considered but is not found persuasive because there was no such allegation. The reference teaches that activated STAT-3 protein was detected in tumor cell lines derived from both primary and metastatic tumor specimens. Applicants arguments appear to hinge on the word “several” in that the reference does not specifically teach which of these several cell lines have the activated STAT-3. This argument has been considered but is not found persuasive because it appears that applicant is merely speculating that activated STAT-3 was not present in the tumor cells derived from primary “metastatic” tumors. Mere speculation, however, would not prevent one of ordinary skill in the art from concluding that activated STAT-3 was not present in metastatic tumor cells. Again, Applicant has argued and discussed the references individually without clearly addressing the combined teachings. Taken together, the combination of the references clearly suggest to one of ordinary skill in the art a *reasonable* expectation of success of determining the metastatic potential of a cancer in an afflicted patient comprising determining the level of activated STAT-3 protein in a sample of tumor tissue wherein an increased level of activated STAT-3 protein indicates an increase metastatic potential.

Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.
Examiner
Art Unit 1642

GBN
March 27, 2003

[Handwritten Signature]
ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600